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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,863	02/08/2000	FREDERIC DONIE	BMID9974US	7240

7590

01/27/2003

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EXAMINER

LI, BAO Q

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 01/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,863

Applicant(s)

DONIE ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 29.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 30.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *sequence letter*.

DETAILED ACTION

Claims 34-43 are pending.

CPA

The request filed on 08/12/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/432,863 is acceptable and a CPA has been established. An action on the CPA follows.

Sequence requirements

This sequence listing submitted on June 11, 2002 does not comply with the sequence rule set forth in 37 CFR 1.821 through 1.825 for the reason(s) as indicated in the sequence error report.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Response to the Amendment

Amendment filed on 10/30/2002 is acknowledged. Claims 16, 17, 19, 23, 25, 29 and 30 are canceled. New claims 34-43 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

The rejection on 112 2nd paragraph for claims 16, 9, 25, 30 are moot because applicants canceled the claims. Since the new claims 34-43 do not recite the undefined language “variants” in the claims, the rejection on “variants” does not apply to the new claims.

The rejection on 112 1st paragraph for claims 16-17, 29, 23, 25 and 29-30 are moot due to Applicants canceled the claims. Since the new claims 34-43 do not recite the undefined language “variants” in the claims, the rejection on “variants” does not apply to the new claims.

Claim Rejections - 35 USC § 103

The rejection on claims 15-17, 19, 21, 23, 25, 29-30 and 32 are moot since Applicants cancel the claims. Because the newly submitted claims read on an antigen mixture consisting of the antigen epitopes selected from two different subtypes of HIV-1 group M, the rejection does not apply to the new claims.

New Grounds of Rejections.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
2. Claims 34-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 34, 39, 41 are unclear for define which precise structures of an antigen of the region II and an antigen from epitope region I are. If Applicants wish to claim the antigen is HIV gp41, please amend the claims to clearly define the antigen is HIV gp41. Moreover, the recitations of claims are not clear to define whether the fragment of amino acids 518-533, 551-560, 570-584, an 581-596 as a whole are the epitope region II or I of HIV gp41 **or** the region of amino acids fragments contains epitopes. If Applicants wish to claim a particular epitope(s) of an antigen, please use more defined language, such as “consisting of” to clearly define the claimed structures of the epitopes. This affects the dependent claims 35-38, 40 and 42.
4. Claim 43 is vague and indefinite in that the metes and bounds of “an antigen” are not defined because the claim use a language “comprising” which is an open language that fails to define whether the antigen only contain “a ten amino acid sequence” or “ a ten amino acids

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sequence” is only part of an antigen structure. If Applicants wish to claim a precise unique antigen consisting of only ten amino acids, please amend the claim by using “consisting of” instead of using “comprising”.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claim 43 is rejected under 35 U.S.C. 102(e) as being anticipated by De Leys (US Patent No. 5/891,640A).

7. De Leys discloses a method for detecting an antibody against HIV-1 by contacting the biological sample with an antigen of a HIV gp41 antigen sequence (SEQ ID NO: 2) with 21 amino acids long, which comprises the exactly 10 amino acid sequence of SEQ ID NO: 36 of the claimed peptide antigen (See line 30 on col. 4 through line 9 on col. 6). Therefore, the claimed invention is anticipated by the cited reference.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

January 23, 2003


JAMES HOUSEL 1/27/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600